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August 22, 2022

VIA ECF

The Hon. Robert B. Kugler
United States District Judge
USDJ, District of New Jersey
Mitchell H. Cohen Building & U.S.
Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Special Master the Hon. Thomas
Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th
Floor
Philadelphia, PA 19103

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK-KMW (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' position with respect to the agenda topics for the conference with the Court on August 24, 2022. Defendants do not expect the need to discuss any confidential materials as part of these agenda items, but reserve the right to move to a confidential setting should the need arise.

1. Defendants' Position Regarding Proposed Third-Party Payor ("TPP") Trial

Plaintiffs and Defendants have met and conferred several times regarding the scope of the 2023 single-plaintiff TPP trial and related fact and expert discovery. Defendants' positions on this issue are set forth below.

Identity of Plaintiffs and Defendants in TPP trial. The parties are in agreement that the Court's proposed 2023 TPP trial should focus on the claims of a single assignor of Plaintiff MSP Recovery Claims, Series, LLC ("MSPRC"). Defendants will be prepared to discuss their proposals with respect to which defendants among ZHP, Teva and Torrent should be in that trial more fully on Wednesday. Identifying the specific MSPRC assignor whose claims will be tried will assist

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with that discussion. Of course, Defendants not participating in the first trial would not be subject to any of the deadlines in the CMO.

Despite the Court’s clear instructions and intent, Plaintiffs continue to argue that the trial should be “on behalf of a certified class, subclass, or part thereof as determined by the Court.” (Email from Adam Slater to Greg Ostfeld (“Slater Email”), Aug. 20, 2022 (Ex. 1).) Plaintiffs’ continued insistence on class treatment is directly contrary to the Court’s repeated admonitions. As the Court well knows, it has repeatedly made clear that it intends to hold an individual TPP trial, and it instructed the parties to meet and confer in accordance with that expectation. *See, e.g.*, July 28, 2022 CMC Hr’g Tr. 27:11 (“I still believe we’re going to go through with the TPP **individual trial** first. That will be the first trial.”) (emphasis added); *id.* 20:13-17 (“the best way to proceed to the first trial is a single TPP plaintiff, which implicates, you know, only maybe a few states’ laws and things of that nature.”). Defendants have also pointed out to plaintiffs that any ruling regarding class certification would likely be the subject of a petition to appeal under Rule 23(f) and thus incompatible with the Court’s envisioned trial schedule.

Status of Claims Not Tried in TPP Trial. Plaintiffs have also proposed claims-splitting. Defendants do not agree to split Plaintiffs’ claims. If Plaintiffs wish to proceed only on their breach-of-warranty, consumer-protection and punitive-damages claims, then their remaining claims against Defendants should be dismissed with prejudice. *See Strader v. U.S. Bank*, No. 2:19-cv-118-NR, 2020 WL 3447776, at *3 (W.D. Pa. June 24, 2020) (dismissing claims against defendants because they “have been improperly split from” another pending case before the court; “The longstanding rule against improper claim splitting prohibits a plaintiff from prosecuting his case piecemeal and requires that all claims arising out of a single alleged wrong be presented in one action.”) (internal quotation marks and citation omitted); *see also Beedle v. Wilson*, No. CIV-06-122-M, 2006 WL 1702502, at *3 (W.D. Okla. June 14, 2006) (“There is no reason why a court should be bothered or a litigant harassed with duplicating lawsuits on the same docket; it is enough if one **complete** adjudication of the controversy be had.”) (internal quotation marks and citation omitted) (emphasis added). If those latter claims are not dismissed, all of the claims should be tried together.

Plaintiffs’ Proposed Order or Stipulation Preserving the Adequacy of TPP Plaintiff in Class Trial. Plaintiffs requested in the parties’ most recent correspondence that, “[i]n the event the Court is inclined to proceed pre-class certification . . . Plaintiffs will . . . request entry of an Order or Stipulation preserving the adequacy of the TPP plaintiff to later serve as a class representative.” (Slater Email.) This request is improper for multiple reasons. As already discussed, the Court has not issued any ruling certifying a proposed TPP class. Accordingly, it would not only be premature to assess the adequacy of MSPRC to represent countless other TPPs, but doing so would be tantamount to issuing an advisory opinion. Moreover, as elaborated in Defendants’ class-certification briefing, MSPRC is neither a typical nor adequate class representative because it will be subject to unique defenses, including the following: (1) the claims it asserts were assigned to it by other TPPs, and the validity of the assignments is subject to dispute; and (2) its serial litigation against insurers in other cases gives rise to a clear conflict of interest.

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Application of Rulings, Findings and Judgment. Plaintiffs have also indicated that they will request that Defendants stipulate that any “rulings, findings, and Judgment” entered in an individual TPP trial case are fully applicable in a “later certified class or subclass.” (See Slater Email.) This categorical request is improper on multiple levels. For starters, because no class has been certified, it would be grossly premature to address what (if any) impact rulings, findings and judgment issued in an individual TPP trial case would have in a later certified class proceeding, if the Court certified a class and its ruling were upheld by the Third Circuit. This is all the more true because the TPP trial will be limited to a select defendant or defendants and have no relevance to any claims against other defendants.

Plaintiffs’ Request for Sequencing of Trials. Plaintiffs indicated in their most recent correspondence that they will ask the Court to “enter an order providing for a sequence of trials to follow the first trial, on behalf of certified class/subclass/or portions thereof, adjudicating the economic loss claims of TPPs/consumer plaintiffs against the remaining manufacturers, thus addressing claims related to the Hetero, Mylan, and Aurobindo API.” (Slater Email.) Again, Defendants believe that this request is inconsistent with the Court’s clear directives. The Court has repeatedly indicated its preference for conducting a single TPP trial; it has never suggested that such a proceeding would ultimately lead to follow-on trials. Nor have Plaintiffs ever raised this “sequencing” concept during the parties’ numerous meet and confers. And sequencing of trials “on behalf of certified class/subclass/or portions thereof” would be all the more improper because there has been no certification ruling.

Further, without specifying which “TPPs/consumers” would be involved in these hypothetical trials, there may be issues related to subject matter jurisdiction, personal jurisdiction, and venue that would be implicated by trials against Mylan, Hetero, and/or Aurobindo. Accordingly, these Defendants object to Plaintiffs’ proposal and reserve all rights.

Discovery. Defendants are agreeable to extending the current case management deadlines, but believe that more time is also needed to allow Defendants time to conduct additional fact discovery of the at-issue MSPRC assignor. Plaintiffs have taken the position that all fact discovery in the MDL is closed. While this is undoubtedly true with respect to the *Valsartan* defendants—who were subject to all-encompassing, multi-year merits discovery concerning issues ranging from alleged liability to damages—the same cannot be said for Plaintiffs, including MSPRC. Rather, discovery as to the proposed class representatives, including MSPRC, was generally limited to class certification issues. This effort to deprive Defendants of the ability to work up their case would be nothing less than a denial of due process.

By way of background, there have now been three phases of fact discovery in the MDL. The first phase, which ended on June 21, 2021, related to document and deposition discovery of the manufacturer defendants, depositions of economic loss and medical monitoring putative class Representatives, and depositions of at least ten personal injury bellwether plaintiffs. See CMO 28, [ECF No. 863](#). The second phase of fact discovery ended on October 4, 2021 and included depositions of the remainder of the 28 personal injury bellwether plaintiffs, depositions of initial treaters and providers agreed to by the parties, and document and deposition discovery of the

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wholesaler and pharmacy defendants. *Id.* Nothing in CMO 28 indicated that there would be no further phases of discovery, and Plaintiffs have sought and been granted additional discovery of the manufacturer defendants related to the *Losartan* and *Ibesartan* cases. *See* Core Discovery Order, CMO [ECF No. 2132](#). Thus, Plaintiffs' position that all fact discovery in the MDL proceeding is complete is inconsistent with the record.

The limited discovery that Defendants were permitted to take as to the TPP class representatives is not sufficient to prepare these cases for trial. With respect to document discovery, the parties entered into a stipulation in December 2020 that limited the scope of Rule 34 requests to the TPP class representatives to issues that pertained directly to class certification. *See* [ECF No. 650](#). Recognizing that additional TPP discovery would be needed in advance of any trial, Defendants served supplemental Rule 34 requests on Plaintiffs on July 19, 2022 and asked Plaintiffs to meet and confer regarding the scope of the same. *See* Letter from Clem Trischler to Adam Slater, July 19, 2022 (Ex. 2). Rather than engage in meaningful meet and confer, Plaintiffs categorically rejected that additional discovery was permitted or necessary. *See* Letter from Ruben Honik to Clem Trischler, July 26, 2022 (Ex. 3). While Defendants have no intention to take duplicative discovery of Plaintiffs, there are discrete categories of information that have not yet been produced by MSPRC's assignors and are necessary for trial. This includes information regarding: (1) prescription claims data and medical costs; (2) post-sale adjustments to prices paid for prescriptions; (3) medical costs associated with hypertension, heart failure, and post-myocardial infarction; (4) diagnosis codes associated with dispensed prescriptions; (5) Medicare reimbursement data; (6) pharmacy benefit manager ("PBM") and TPP contracts, member communication and plan design documents; (7) TPP agreements with other pharmaceutical entities; and (8) Pharmacy and Therapeutics Committee ("P&T Committee") minutes and decisions.

Likewise, while Plaintiffs note that Defendants have already taken 30(b)(6) depositions of MSPRC, Defendants are entitled to fact witness depositions as well. *See, e.g., Seavey v. Globus Med. Inc.*, No. 11-2240 (RBK/JS), 2012 WL 12902792 (D.N.J. Dec. 14, 2012) (holding that plaintiffs were entitled to depose witness in individual capacity notwithstanding overlap with prior 30(b)(6) deposition; "Just as plaintiffs may not dictate to defendant how it must take its discovery, defendant may not dictate to plaintiffs that they must take relevant testimony from a Rule 30(b)(6) witness rather than Giordano."); *Sonrai Sys., LLC v. Romano*, No. 16 CV 3371, 2019 WL 11704216, at *2 (N.D. Ill. Apr. 25, 2019) (requiring fact witness depositions to proceed after Rule 30(b)(6) deposition). For example, Defendants must be allowed to depose the relevant PBMs, who administered the assignor's prescription claims and one or more P&T Committee members who were involved in creating the formularies employed by MSPRC's assignor, and other individuals who may have knowledge about the reimbursements that MSPRC's assignor received from the federal government or other sources to offset money they spent covering Defendants' valsartan. Additional depositions may also be required once MSPRC's document production is complete to address issues raised by new documents.

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2. The Parties' Position and Proposal Regarding Motion to Seal

The parties have been reviewing the confidentiality designations for materials submitted in connection with the class certification briefing and Rule 702 motions, which amounted to hundreds of documents filed with some level of confidentiality designation. As confirmed by the Court on the record at the June 29, 2022 Case Management Conference, the deadline for the parties to submit the motion to seal with respect to the class certification briefing and Rule 702 class certification expert briefing was to be extended until 60 days from completion of the parties' meet and confer on the motion to seal, which occurred on July 15, 2022. Accordingly, the current deadline for the parties to file their motion to seal is September 13, 2022.

The parties have already made significant progress, and have identified categories of documents that were previously treated as confidential but that the parties have now agreed should either be filed publicly and/or filed with appropriate redactions. The parties intend to file such amended exhibits on the public docket in the interest of public access. The parties continue to work cooperatively to identify the materials for which the parties agree on the confidential status and which materials remain in dispute.

The parties propose that in the interest of efficiency, their submission to the Court address only materials for which the confidential status remains in dispute in lieu of submitting an index of all documents as contemplated by Local Civil Rule 5.3(c). The parties believe that this proposal serves the interests of judicial economy by permitting the Court and the parties to focus their resources on the disputed materials. The parties' proposal also accounts for the public's interest in disclosure, as any materials that the parties have agreed should remain confidential have already been subjected to adversarial review.

Given the high volume of materials that require individualized review and the ongoing negotiations between the parties, additional time may be necessary in which the parties can complete their negotiations and prepare the amended exhibits for the public docket. Accordingly, the parties propose that they confer by September 13, 2022, to assess the status of negotiations and the scope of disputed materials, and determine subsequent deadlines for their submission based on the volume of disputed materials that remain. The parties would then submit an agreed-upon proposed schedule to the Court for the submission and filing of amended exhibits.

3. PFS Deficiency Issues

Cases Addressed at the July 28, 2022 Case Management Conference:

The Court issued 10 show cause orders returnable at the August 24, 2022 Case Management Conference:

1. *Donna King v. Doe et al.* – 20-cv-8814
2. *Margaret Tolley v. Mylan Laboratories et al.* – 21-cv-10130
3. *Katherine Peyton v. Mylan et al.* – 21-cv-09063

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4. *Michael Shemes v. Aurobindo et al.* – 21-cv-20204
5. *Leona Branch v. Mylan, et al.* – 22-cv-582
6. *Richard Vindigni v. Prinston, et al.* – 21-cv-2361
7. *Robert Cooper v. ZHP, et al.* – 22-cv-1635
8. *Robert Dais v. Mylan, et al.* – 22-cv-518
9. *Elie Greene v. Aurobindo, et al.* – 21-cv-3214
10. *Majorie Smith v. Camber, et al.* – 21-cv-12740

The issues in the *Cooper* and *Peyton* matters are resolved, and the show cause orders may be withdrawn.

The issues in the *Greene*, *Vindigni*, and *Tolley* matters remain unresolved, but the parties are working towards a resolution and request a one-month extension of the order to show cause until the September Case Management Conference.

The issues in the *King*, *Shemes*, *Branch*, *Dais*, and *Smith* matters remain unresolved, and Defendants request their dismissals.

Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases was previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on August 18, 2022, and a global meet and confer was held on August 22, 2022. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the August 24, 2022 Case Management Conference:

| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|----|---|-------------------------|---|---|------------------------|
| 1. | Debra Stiles v. ZHP et al. | 22-cv-01987 | Pittman, Dutton, Hellums, Bradley & Mann P.C. | Missing medical expenses | 6/22/22 |
| 2. | E.O. Nancy Mastbergen v. Hetero Drugs, Ltd., et al. | 22-cv-38 | Oliver Law Group P.C. | XI.A.1 – The following providers were identified in the | 5/12/22 |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|--|-----------|------------------|----------|---|-----------------|
| | | | | <p>Second Amended PFS: Advanced Radiology Services PC; Coran Alternate Site Services Inc.; Visiting Nurse Services of Western Michigan; Cancer and Hematology Centers of Western Michigan PC; Allcare Plus Pharmacy Inc.; Michigan Pathology Specialists; West Michigan Anesthesia PC; Ees Western Michigan PC; Life Ems Inc.; and Veracyte Inc. Please produce properly executed and undated authorizations for each of the foregoing health care providers and treatment facilities.</p> <p>XI.B.18 – An explanation of benefits was produced, but still no billing records</p> | |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|----|--|------------------|------------------|---|-------------------|
| | | | | were produced from the providers themselves | |
| 3. | Jim Smith v. ZHP, et al. | 22-cv-01245 | Hollis Law | No PFS Filed | PFS Due - 7/2/22 |
| 4. | Frank Trimboli v. Torrent, et al. | 20-cv-01601 | Carlson Law | No PFS Filed | PFS Due - 7/4/22 |
| 5. | Walid Elganam v. ZHP et al. | 22-cv-02873 | Carlson Law Firm | No PFS Filed | PFS Due - 7/17/22 |
| 6. | Richard Williams v. ZHP et al. | 20-cv-20602 | Alvin Pittman | No PFS Filed | PFS Due - 7/27/22 |
| 7. | Eric Thompson v. ZHP et al. | 21-cv-19973 | Levin Papantonio | Largely deficient PFS, including no signed declaration, no authorizations, no medical expense records | 7/13/22 |
| 8. | Judith Ross v. ZHP et al. | 22-cv-02387 | Levin Papantonio | Missing medical expense records | 7/18/22 |
| 9. | E.O. Christopher Gallagher, et al. v. Hetero Drugs, Ltd., et al. | 22-cv-00930 | Stark & Stark | IV.C.1-IV.C.3 – Failed to provide the end date for usage of Walgreens for Plaintiff's prescriptions in the Seventh Amended PFS. | 5/1/22 |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|--|-----------|------------------|----------|---|-----------------|
| | | | | <p>XI.A.1 – The produced authorizations are dated. Please produce properly executed and undated authorizations for each identified provider, treatment facility, and pharmacy. Also, no health care authorizations were produced for: Vitas Nazareth Hospital; Alliance Cancer Center; Newtown Ambulance; St. Claire Pharmacy; or Walgreens.</p> <p>XI.A.2 – No tax returns authorizations were produced.</p> <p>XI.B.2 – No Walgreens pharmacy or St. Clare Pharmacy records produced.</p> <p>XI.B.18 – Still no billing records were produced</p> | |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|-----|---|------------------|-----------------|---|-----------------|
| | | | | with the Seventh Amended PFS. | |
| 10. | Kerry Jackson, Individually and o/b/o E.O. Janice Jackson v. Hetero Drugs, Ltd., et al. | 22-cv-00154 | Hollis Law Firm | I.E.4 – Failed to identify the state, court, and case number in connection with the answering Plaintiff's authority to act as a representative on behalf of the deceased Plaintiff. Also, failed to produce supporting documentation demonstrating appointment of answering Plaintiff's authority to act as a representative on behalf of the deceased Plaintiff. XI.B.18 – No corresponding billing record produced for the identified claimed medical expense with a date of service from 5/10/2017. XII – No declaration produced with the | 5/11/2022 |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
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| | | | | Third Amended PFS. | |

First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiff leadership on August 18, 2022, and a global meet and confer was held on August 22, 2022. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|----|---|------------------|------------------------|--|-----------------|
| 1. | Benita King v. ZHP et al | 22-cv-1628 | Levin Papantonio | Need medical expenses | 7/18/22 |
| 2. | Estate of Charles Bernhardt v. Walgreens, et al. | 22-cv-4330 | Parafinczuk Wolf, P.A. | Multiple deficiencies; need authorizations | 8/2/22 |
| 3. | Francesco Poma, Individually and o/b/o E.O. Giuseppa Poma v. Hetero Drugs, Ltd., et al. | 22-cv-01118 | Hollis Law Firm, P.A. | III.G.c – Failed to provide any substantive response regarding the monetary amount for the identified claimed medical expense. XI.B.2 – No pharmacy records produced for: Sam's Club Pharmacy; or Walgreens | 5/26/22 |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|----|---|-------------------------|------------------|---|------------------------|
| | | | | <p>Pharmacy. Also, no medical records were produced for the identifeid physicians whom prescribed Valsartan to Plaintiff, being: Dr. Pasquale Laderosa; Paula Leferman, NP; or Nicole Adamic, PA.</p> <p>XI.B.18 – No billing records produced.</p> | |
| 4. | Henry Parker, Jr. v. Hetero Drugs, Ltd., et al. | 21-cv-19401 | Levin Papantonio | <p>III.G.a-III.G.c – Failed to provide any substantive responses to the request to identify Plaintiff's claimed medical expenses, including: the name of the healthcare provider for each claimed medical expense; and the monetary amount of each claimed medical expense.</p> <p>XI.B.18 – No billing records produced.</p> | 2/18/22 |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|-----|--|-----------------------------|------------------|---------------------|------------------------|
| 5. | Carrie Collins v. Aurobindo Pharma, et al. | 19-cv-16386/ 19-cv-16387 | Haffner Law PC | No PFS Filed | PFS Due - 7/27/22 |
| 6. | Maritza Hernandez v. Aurobindo et al | 22-cv-3288 | Levin Papantonio | No PFS Filed | PFS Due - 7/31/22 |
| 7. | Jacqueline Wallaert v. Aurobindo, et al | 22-cv-1526 | Nabers Law | No PFS Filed | PFS Due - 8/1/22 |
| 8. | Robert Lewis v. Aurobindo et al | 22-cv-2524 | Nabers Law | No PFS Filed | PFS Due - 8/1/22 |
| 9. | Robert Bailey v. Mylan et al | 22-cv-1518 | Nabers Law | No PFS Filed | PFS Due - 8/1/22 |
| 10. | Thomas Amoia v. Mylan et al | 22-cv-2438 | Nabers Law | No PFS Filed | PFS Due - 8/1/22 |
| 11. | Robert Parker v. Hetero, et al | 22-cv-2419 | Nabers Law | No PFS Filed | PFS Due - 8/1/22 |
| 12. | Estate of Clifford Conley v. Aurobindo et al | 22-cv-3323 | Nabers Law | No PFS Filed | PFS Due - 8/2/22 |
| 13. | Gracie Ellis v. ZHP et al | 22-cv-3382 | Nabers Law | No PFS Filed | PFS Due - 8/2/22 |
| 14. | Willie Quarles v. Aurobindo et al | 22-cv-3385 | Nabers Law | No PFS Filed | PFS Due - 8/2/22 |
| 15. | Mona Clark v. Aurobindo et al | 22-cv-3392 | Nabers Law | No PFS Filed | PFS Due - 8/2/22 |

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|-----|-----------------------------------|-------------------------|------------------|---------------------|------------------------|
| 16. | Brian Thompson v. Aurobindo et al | 22-cv-3438 | Nabers Law | No PFS Filed | PFS Due - 8/3/22 |
| 17. | Renae Bishop v. Mylan et al | 22-cv-3441 | Nabers Law | No PFS Filed | PFS Due - 8/3/22 |
| 18. | Candace King-Branch v. ZHP et al | 22-cv-3856 | Levin Papantonio | No PFS Filed | PFS Due - 8/15/22 |
| 19. | Vincent Shannon v. Mylan et al | 22-cv-3870 | Levin Papantonio | No PFS Filed | PFS Due - 8/15/22 |
| 20. | Larry Bass v. Hetero et al | 22-cv-4151 | Nabers Law | No PFS Filed | PFS Due - 8/20/22 |
| 21. | Bobby Yount v. ZHP et al | 22-cv-4155 | Nabers Law | No PFS Filed | PFS Due - 8/20/22 |
| 22. | Rose McCarty v. ZHP et al | 22-cv-4164 | Nabers Law | No PFS Filed | PFS Due - 8/21/22 |

Respectfully Submitted,



Jessica Davidson Miller

cc: All counsel of record (via ECF)